K131625

SECTION G
510(K) SUMMARY

In accordance with 21CFR 807.92

1.0 Submitter Information

Name: Absolute Imaging Solutions

Address: 8205 B&G Court
Stokesdale, NC 27357 USA

Phone: 336-643-2000
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OCT 03 2013

Contact Person: Mark Shina, President

Date of Submission: 22 May 2013

2.0 Device Identification

Name of Device: AnyScan-S SPECT Imaging System

Common Name: Gamma Camera – SPECT Imaging System

Classification Name: Emission Computed Tomography System (ECT)

3.0 Predicate Devices

1. Symbia-E – Siemens [**K072567**]

4.0 Intended Use / Indications for Use

For use to detect or image the distribution of radionuclides in the body or organ, using the following techniques: planar imaging, whole body imaging and tomographic imaging.

5.0 Technological Characteristics

The AnyScan-S is a Single- or Dual-Detector Gamma Camera System that supports planar static, dynamic as well as SPECT and whole body imaging applications with high patient throughput requirements.

As such, the AnyScan-S SPECT Imaging System raises no new issues of safety or efficacy.

6.0 Performance Testing and Data

Performance testing was performed using NEMA NU1 phantoms, under the NEMA Standard test protocols. In all cases, performance of the AnyScan-S device met or exceeded that of predicate devices.

Clinical images were obtained using the AnyScan-S in human subjects. Tomographic image quality was at least equal to images produced by reference predicate devices.

Furthermore, electrical safety testing has been performed and found to meet applicable standards and defined acceptance criteria.

7.0 Substantial Equivalence

The AnyScan-S SPECT Imaging System has the same intended use, similar principles of operation, and consistent technological characteristics as the predicate devices. Thus, the AnyScan-S is substantially equivalent to the predicate devices and no new safety or effectiveness concerns are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

Absolute Imaging Solutions
% Mr. Mark Shina
President
8205 B&G Court
STOKESDALE NC 27357

Re: K131625
Trade/Device Name: AnyScan-S SPECT Imaging System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS
Dated: September 18, 2013
Received: September 27, 2013

Dear Mr. Shina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director, Division Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131625

Device Name: AnyScan-S

Indications for Use:

For use to detect or image the distribution of radionuclides in the body or organ, using the following techniques: planar imaging, whole body imaging and tomographic imaging.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off) Division of
Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) k131625